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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Complete If Known

Application Number	10/560,385
Filing Date	January 12, 2007
First Named Inventor	Michael G. Orchard, et al.
Art Unit	1625
Examiner Name	John Mabry

(as many sheets as necessary)

Sheet

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of

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Attorney Docket No: AC-51-US

## US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		4,407,809	10-04-1983	Junge et al.	
		4,639,436	01-1987	Junge et al.	
		5,051,407	09-24-1991	Boshagen et al.	
		5,798,366	8-25-1998	Platt et al.	
		6,046,214	04-04-2000	Kristiansen et al.	
		6,426,198	7-30-2002	Carstea et al.	
		6,495,570	12-17-2002	Jacob et al.	
		6,683,076	01-2004	Walkley et al.	
		7,256,005	08-2007	Zitzmann et al.	
		2001/0044453	11-22-2001	Jacob et al.	
		US 2004/0019082	01-29-2004	Van der Spoel et al.	
		20060058349	3-2006	Hussein et al.	
		20060074107	04-2006	Butters et al.	
		20060111400	05-2006	Hussein et al.	
		20070112028	05-2007	Orchard et al.	
		20080234324	09-2008	Scopes et al.	

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(Use as many sheets as necessary)					
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FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	†
		DE 3024901 A (and Translation)	01-28-1982	Dietar et al.	
		EP 0491041	24 Jun 1992	Nippon Shinyaku Co. Ltd.	
		EP 698102	01 Mar 2006	Roche Diagnostics GmbH	
		EP 698012	29 Jan 1997	G.D. Searle & Co.	
		JP-1-02/306962	20 Dec 1990	Meiji Seika Kaisha Ltd.	
		JP 3-24057	01 Feb 1991	Tosoh Corp.	
		JP H02-306962 (and Translation)	12-20-1990	Hiroshi et al.	
		WO 92/00277	09 Jan 1992	Nippon Shinyaku Co., Ltd.	
		WO 98/02161	22 Jan 1998	Universiteit Van Amsterdam	
		WO 98/30219	16 Jul 1998	Monsanto Company	
		WO 99/24401	20 May 1999	G.D. Searle & Co.	
		WO 00/33843	15 Jun 2000	G.D. Searle & Co., et al.	
		WO 00/56334	28 Sep 2000	The Trustees of Boston College	
		WO 00/62780	26 Oct 2000	Oxford Glycosciences (UK) Ltd.	
		WO 01/10429	15 Feb 2001	Zitzmann et al.	
		WO 02/055489	07-18-2002	The Trustees of Columbia University in the City of New York	
		WO 04/007453	22 Jan 2004	Oxford Glycosciences (UK) Ltd.	
		WO 04/007454	22 Jan 2004	Oxford Glycosciences (UK) Ltd.	
		WO 04/111001	23 Dec 2004	Oxford Glycosciences (UK) Ltd.	
		WO 04/111002	23 Dec 2004	Oxford Glycosciences (UK) Ltd.	
		WO 05/068426	28 Jul 2005	Cell-Tech R&D Limited	

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			†
		ABE et al., Induction of glucosylceramide synthase by synthase inhibitors and ceramide, BBA, 1299, 333-341 (1996).			
		ALTER, M., GM1 ganglioside for acute ischemic stroke- trial design issues, Ann. NY Acad. Sci., 1998, 845, pp. 391-4011.			
		ASANO, K., "New entry for asymmetric deoxyazasugar synthesis: syntheses of deoxymannojirimycin, deoxyaltrojinimycin and deoxygalactostatin", Chem. Commun., 1999, pp. 41-42.			
		ASANO, N. et al., "Novel α-L-fucosidase inhibitors from the bark of angylocalyx pynaertii (leguminosae), Eur. J. Biochem., 2001, 268, pp. 35-41.			

EXAMINER

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Substitute Disclosure Statement Form (PTO-1449)  
\* EXAMINER: initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. A separate signature, date and date of consideration must be placed in the space provided. If English language translation is attached, it should be placed in the space provided.

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Sheet	3	of	4
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- BARILE, P.L. et al., "Double reductive amination of L-arabino-hexos-5-uloses: a diastereoselective approach to 1-deoxy-D-galactostatin derivatives (#)(\*)", *Tetrahedron*, 1997, 53(9), pp. 3407-3416.
- BAXTER, E.V. et al., "Expedient synthesis of azasugars by the double reductive amination of dicarbonyl sugars", *J. Org. Chem.*, 1994, 59, pp. 3175-3185.
- BERG et al., Herbicidal composition containing piperidine derivatives, CAPLUS, 96:117597 (1982).
- Biochemical Genetics, A Laboratory Manual, Oxford University Press.
- BOESHAGEN et al., Use of hydroxymethyl-3,4,5-trihydroxypiperidines as antiviral agents, CAPLUS, 113:126581 (1990).
- Br. J. Cancer, 1999, 81(3), pp.423-430.
- BRAMER, S.L. et al., Biologic activity of 5-deoxy-5-fluorouridine by rectal administration, *Pharmaceutical Res.*, 1989, 6(4), 318-322.
- BUTTERS et al., Therapeutic applications of imino sugars in lysosomal storage disorders, *Current Topics in Medicinal Chemistry*, 3, 561-574 (2003).
- CAREY, *Organic Chemistry*, 2<sup>nd</sup> Edition, Pages 28-29, 268-271.
- CRUZ, J.C. et al., Fate of Endogenously Synthesized Cholesterol in Niemann-Pick Type C1 Cells, *The Journal of Biological Chemistry*, 2000, Issue of December 29, Vol. 275, No. 52, pp. 41309-41316.
- DRAYER et al., *Clinical and Pharmacology and Therapeutics*, 1986.
- EZURE et al., Preparation of 1-deoxygalactostatin derivatives as  $\beta$ -galactosidase inhibitors, CAPLUS, 116:236093 (1992).
- FOUAEC, S. et al., Lipophilic prodrugs of 1-deoxynojirimycin derivatives, *Tetrahedron Letts.*, 2000, 41, 7313-7315.
- FOWLER, P.A. et al., Synthesis and activity towards yeast  $\alpha$ -glucosidase of 1,5-dideoxy-1,5-imino-L-iditol (1-deoxy-L-idoynojirimycin), *Carbohydr. Res.*, 1993, 246, 377-381.
- GREENE, Protective groups in organic synthesis, Wiley-Interscience Publication, pages:cover, 10, 11, 29 (1982).
- HUGEL, H.M. et al., Stereoselective electrophilic cyclizations of  $\delta$ -aminoalkenes derived from carbohydrates: synthesis of polyhydroxypiperidines, *Aust. J. Chem.*, 1998, 51, pp. 1149-1155.
- HUTT and O'GRADY, *Drug Chirality*, 1996.
- JARANOWSKA, A. et al., Platelet-activating factor production by human fetal microglia, *Mol. & Chem. Neuropathol.*, 1995, 24, pp. 95-106.
- KATO et al., Biological properties of D- and L-1 deoxyazasugars, *J. Med. Chem.*, 48, pp. 2036-2044, (2005).
- KAZMAIER, U. et al., A short synthesis of polyhydroxylated piperidines by adol reaction of chelated amino acid ester enolates, *Eur. J. Org. Chem.*, 1998, pp. 1833-1840.
- KURIHARA et al., Preparation of N-substituted 1-deoxynojirimycins as tumor metastasis inhibitors, CAPLUS, 114:185939 (1991).
- LE MERRER et al., Synthesis of azasugars as potent inhibitors of glycosidases, 5(3), 519-533, (1997).
- LIN and LU et al., Role of Pharmacokinetics and Metabolism in Discovery and Development, 1997.

DATE CONSIDERED

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 6009. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (column 2) Applicant is to place a check mark here if English language Translation is attached

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(Use as many sheets as necessary)

Sheet	4	of	4	Attorney Docket No: AC-51-US
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		LIU, Y. et al., Alleviation of neuronal ganglioside storage does not improve the clinical course of the Niemann-Pick C disease mouse, Human Molecular Genetics, 2000, Vol. 9., No. 7, pp. 1087-1092.	
		MELLOR, High-performance cation-exchange chromatography and pulsed amperometric detection for the separation, detection, and quantitation of N-alkylated imino sugars in biological samples, Analytical Biochemistry, XP-001055984, 284, 136-142 (2000).	
		MORRISON et al., Organic Chemistry, 5 <sup>th</sup> Edition, Pages 138-141.	
		OVERKLEEF et al., Generation of specific deoxynojirimycin-type inhibitors of the non-lysosomal glucosylceramidase, J. of Biol. Chem. 23(43), 27108-27114, (1994).	
		PLATT et al., N-Butydeoxynojirimycin is a novel inhibitor of glycolipid biosynthesis, 269(11), 8362-8365 (1994).	
		PLATT, F.M. et al., New Therapeutic Prospects for the Glycosphingolipid Lysosomal Storage Diseases, Biochemical Pharmacology, 1998, Vol. 56, pp. 421-430.	
		POITOUT, L. et al., Synthesis of azasugars. Part 1 - Simerization of polyhydroxylated piperidines, Tetrahedron Letts., 1996, 37(10), pp. 1609-1612.	
		RAO, V.S. et al., Regioselective eliminations in reactions of carbohydrate derivatives with superoxide, or with borohydride in 2-propanol, Can. J. Chem., 1981, 59(2), pp. 333-338.	
		REITZ, A.B. et al., Pyrrolidine and piperidine aminosugars from dicarbonyl sugars in one step. Concise synthesis of 1-deoxynojirimycin, Tetrahedron Letts., 1990, 31(47), pp. 6777-6780.	
		SCHALLER et al., Total synthesis of (+)- and (-)-1-deoxynojirimycin (1,5-dideoxy-1,5-imino-D- and L-glucitol) and of (+)- and (-)-1-deoxyidonojirimycin(1,5-dideoxy-1,5-imino-D and L-iditol) via furoisoxazoline-3-aldehydes, Carbohydrate Res., 314, 25-35, (1998).	
		SILVA, et al., Advances in Prodrug Design, Mini-Reviews in Medicinal Chemistry, 2005, Vol. 5, pp. 893-914.	
		TESTA et al., Racemates Versus Enantiomers in Drug Development, 1990.	
		VAN DEN BROEK et al., Chemical modification of aza sugars, inhibitors of N-glycoprotein-processing glycosidases and of HIV-1 infection, CAPLUS, 19:96007, (1993).	
		VAN DER SPOEL et al., Proc. Natl. Acad. Sci. USA, 99(26), 17173-17178 (2002).	
		WU, W. et al., Synthesis and Biological Activity of a Gemcitabine Phosphoramidate Prodrug, J. Med. Chem., 2007, Vol. 50(15), pp. 3743-3746.	
		YILDIZ, Y. et al., Mutation of $\beta$ -glucosidase 2 causes glycolipid storage disease and impaired male fertility, The Journal of Clinical Investigation, 2006, Vol. 116, No. 11, pp. 2985-2994.	
		ZERVAS, M. et al., Critical role for glycosphingolipids in Niemann-Pick disease type C, Current Biology, 2001, 11, pp. 1283-1287.	

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